REMARKS

A. The Claim Objections Are Overcome

The spelling of "subarachnoid" in the preamble of the independent claims has been corrected to address the claim objections.

B. The Anticipation Rejection Based on Aebischer Is Overcome

Claims 1, 7, 11, 13, 21, 24, 27, 28, and 65 stand rejected as being anticipated over US 5,487,739 to Aebischer. Applicant has amended independent claim 1 to distinguish Aebischer. The rejection is overcome.

1. Claim 1

Claim 1 is directed to a method of navigating a spinal subarachnoid space in a living being. Claim 1 has been amended to recite (underlined text is added):

> percutaneously introducing a guidewire <u>in a direction through an introducer and</u> into the spinal subarachnoid space at an entry location, the guidewire being sufficiently flexible to navigate the spinal subarachnoid space<u>, the introducer having a distal end</u>;
>
> <u>advancing the guidewire in another direction beyond the distal end of the introducer</u>; . . . .

Aebischer discloses percutaneously introducing a guidewire (102) in a direction through an introducer (guidance needle 100), but does not teach or suggest advancing guidewire 102 in **another direction beyond the distal end of guidance needle 100**. This is clear from the description in Aebischer, which states that the distal ends of the guidance needle 100 and guidewire 102 both are placed in essentially the same location: either "at or proximate the treatment site 12'" (col. 9, lines 30-35; col. 10, lines 6-10). This is also clear from FIG. 2B of Aebischer. To the extent that FIG. 2B shows guidewire 102 as having extended beyond the distal end of guidance needle 100, the two are **aligned**, and it is clear that guidewire 102 was not advanced **in another direction** beyond the distal end of guidance needle 100. For this reason,

the anticipation rejection of independent claim 1 is overcome and should be withdrawn. Claims 7, 11, 13, 21, 24, 27, and 28 depend from claim 1 and are novel over Aebischer for at least the same reason as claim 1.

2. Claim 65

Independent claim 65 has not been amended to distinguish Aebischer because no amendment is necessary. It recites a method of navigating a spinal subarachnoid space in a living being, comprising:

> percutaneously introducing a device into the spinal subarachnoid space at an entry location, the device having a first passageway sized to slidably receive, and work with, at least a guidewire;
>
> advancing the device within the spinal subarachnoid space at least more than 10 centimeters from the entry location;
>
> introducing a penetration apparatus through the first passageway of the device, the penetration apparatus including an outer sleeve element and an inner puncture element, the outer sleeve element and the inner puncture element being slidably coupled together; and
>
> puncturing the pia matter using the penetration apparatus.

The Office asserts that "a penetration apparatus (100) is inserted through the first passageway of cannula (20) with an inner puncture element (100B) which is used to puncture the pia matter (Fig. 4)." Action at p. 3. This is factually incorrect.

Aebischer fails to disclose or suggest "introducing a penetration apparatus through the first passageway of the device, the penetration apparatus including an outer sleeve element and an inner puncture element, the outer sleeve element and the inner puncture element being slidably coupled together[.]" First, Aebischer FIG. 4 pertains to a section of the cranium that was accessed via cutting through skull bone. Thus, FIG. 4 does not disclose the result of "percutaneously introducing a device into the spinal subarachnoid space at an entry location" as specified in claim 65. *See* Specification at page 14, line 31 to page 15, line 3 ("Furthermore, as

used in this document (including the claims), 'percutaneously introducing' a device means to introduce the device ***without first cutting away bone through, for example, craniotomy or drilling burr holes***.") (emphasis added). Furthermore, there is no disclosure anywhere in Aebischer of inserting guidance needle 100 **through** cannula 20. Instead, guidance needle 100 is described and shown as the device that is used to initially access the subarachnoid space. *See* col. 9, lines 15-32; FIG. 2A. A guidewire 102 is then inserted through the guidance needle, the guidance needle is removed (leaving the guidewire), a dilator is optionally passed over the guidewire, and then catheter 20 can be passed over the guidewire (col. 10, lines 40-43) or in the space left by the guidewire and dilator.

Accordingly, the anticipation rejection of independent claim 65 is overcome and should be withdrawn. The claims depending from claim 1 that were rejected are novel over Carroll for at least the same reason.

C. The Anticipation Rejection Based on Carroll Is Overcome

Claims 1, 4, 12, 17, 19, and 20 stand rejected as being anticipated over US 6,761,715 to Carroll. Applicant traverses.

Carroll was filed February 5, 2002. This application was filed July 13, 2001. Thus, the Office must rely on the disclosure of the provisional application to which Carroll claims priority (Serial No. 60/286,636) to establish anticipation. Nothing in the provisional application teaches or suggests percutaneously introducing a guidewire into the spinal subarachnoid space at an entry location, and percutaneously introducing a device **over the guidewire** and into the spinal subarachnoid space, the device having a first passageway sized to slidably receive, and work with, at least the guidewire, and the **guidewire being positioned in the first passageway**. The only guidewire disclosed in the provisional application is external guide wire 44, which is

located **outside** of (not in the passageway of) tube 20 of cryocatheter 18. Carroll fails to anticipate claim 1 for at least this reason, and the rejection should be withdrawn. Claims 4, 12, 17, 19, and 20 depend from claim 1 and are novel over Carroll for at least the same reason as claim 1.

D. The Obviousness Rejection of Claims 2 and 22 Is Overcome

Claims 2 and 22 stand rejected as being obvious over Aebischer in view of US 6,328,694 to Michaeli. Claims 2 and 22 depend from claim 1 and are novel over Aebischer for at least the same reason as claim 1. Michaeli does not cure Aebischer's deficiency. Therefore, claims 2 and 22 are nonobvious over the asserted combination, and the rejection should be withdrawn.

E. The Obviousness Rejection of Claim 3 Is Overcome

Claim 3 stands rejected as being obvious over Aebischer. As explained above, while Aebischer discloses percutaneously introducing a guidewire (102) in a direction through an introducer (guidance needle 100), it does not teach **or suggest** advancing guidewire 102 in **another direction beyond the distal end of guidance needle 100**. Therefore, the obviousness rejection of claim 3 is overcome and should be withdrawn.

F. The Obviousness Rejection of Claims 5, 6, 68, and 69 Is Overcome

1. Claims 5 and 6

Claims 5 and 6 stand rejected as being obvious over Aebischer in view of US 6,379,331 to Barbut. Claims 5 and 6 depend from claim 1 and are novel over Aebischer for at least the same reason as claim 1. Barbut does not cure Aebischer's deficiency. For example, Barbut's needle 66 fails to teach or suggest the recited flexibility of the claimed guidewire. Therefore, claims 5 and 6 are nonobvious over the asserted combination, and the rejection should be withdrawn.

2. Claims 68 and 69

Independent claim 68 and dependent claim 69 stand rejected as being obvious over Aebischer in view of Barbut. Claim 68 recites a method of navigating a spinal subarachnoid space in a living being, comprising:

> percutaneously introducing a device into the spinal subarachnoid space at an entry location, the device having a first passageway sized to slidably receive, and work with, at least a guidewire;
>
> advancing the device within the spinal subarachnoid space at least more than 10 centimeters from the entry location; and
>
> accessing at least one ventricle located within the head with a second device introduced through the first passageway of the device.

The Office admits that Aebischer fails to teach "accessing at least one ventricle located within the head with a second device introduced through the first passageway of the device[,]" but asserts that Barbut teaches "that a catheter is used to access a lateral ventricle that the catheters [sic] can be used to drain fluid from the body." Action at p. 6. However, the only access to the lateral ventricle that Barbut discloses is through **a skull burr hole** (col. 4, lines 21-25; col. 9, lines 16-18), **not** through a second device that is introduced through the passageway of a first device that has been **percutaneously introduced** into the spinal subarachnoid space. Thus, even taking the references together, all of the limitations of claim 68 are not disclosed or suggested, and the rejection of both claims is overcome.

G. The Obviousness Rejection of Claim 8 Is Overcome

Claim 8 stands rejected as being obvious over Aebischer in view of US 6,004,262 to Putz. Claim 8 depends from claim 1 and is novel over Aebischer for at least the same reason as claim 1. Putz does not cure Aebischer's deficiency. Therefore, claim 8 is nonobvious over the asserted combination, and the rejection should be withdrawn.

H. The Obviousness Rejection of Claims 8 and 64 Is Overcome

1. Claim 8

Claim 8 stands rejected as being obvious over Aebischer in view of US 2004/0147433 to Keep. Claim 8 depends from claim 1 and is novel over Aebischer for at least the same reason as claim 1. Keep does not cure Aebischer's deficiency. Therefore, claim 8 is nonobvious over the asserted combination, and the rejection should be withdrawn.

2. Claim 64

Independent claim 64 stands rejected as being obvious over Aebischer in view of Keep. Claim 64 recites a method of navigating a spinal subarachnoid space in a living being, comprising:

> percutaneously introducing a device into the spinal subarachnoid space at an entry location, the device having a first passageway sized to slidably receive, and work with, at least a guidewire;
>
> advancing the device within the spinal subarachnoid space at least more than 15 ~~10~~ centimeters from the entry location;
>
> introducing a radioactive pellet through the first passageway of the device; and
>
> placing the radioactive pellet within the living being in order to irradiate a tumor.

As the underlining and strike-through above shows, claim 64 has been amended to recite advancing the device within the spinal subarachnoid space at least more than 15 centimeters from the entry location. Aebischer fails to teach or suggest advancing any structure that far. Keep fails to cure this deficiency. Accordingly, the obviousness rejection is overcome and should be withdrawn.

I. The Obviousness Rejection of Claims 25, 26, and 67 Is Overcome

1. Claims 25 and 26

Claims 25 and 26 stand rejected as being obvious over Aebischer in view of US 6,330,466 to Hofmann. Claims 25 and 26 depend from claim 1 and are novel over Aebischer for at least the same reason as claim 1. Hofmann does not cure Aebischer's deficiency. Therefore, claims 25 and 26 are nonobvious over the asserted combination, and the rejection should be withdrawn.

2. Claim 67

Independent claim 67 stands rejected as being obvious over Aebischer in view of Hofmann. Claim 67 recites a method of navigating a spinal subarachnoid space in a living being, comprising:

> percutaneously introducing a device into the spinal subarachnoid space at an entry location, the device having a first passageway sized to slidably receive, and work with, at least a guidewire;
>
> advancing the device within the spinal subarachnoid space at least more than 10 centimeters from the entry location;
>
> introducing an electroencephalography electrode through the first passageway of the device; and
>
> placing the electrode proximate brain tissue.

The Office admits that Aebischer fails to teach "the use of an electrode placed near the brain[,]" but asserts that Hofmann cures this deficiency and that it would have been obvious "to use the insertion procedure of Aebischer in order to insert the electrode of Hofmann near the brain tissue in order to provide treatment to a patient." Action at p. 7. However, Hofmann concerns stereotactic neurosurgery, which generally involves non-percutaneous access to the brain, and there is no suggestion in Hofmann of gaining access to the brain percutaneously. Furthermore, the brain access disclosed by Aebischer appears in FIG. 4 as access achieved via cutting through

skull bone. Thus, even taking the references together, all of the limitations of claim 67 are not disclosed or suggested, and the rejection is overcome.

J. Petition for Extension of Time in This and Future Responses

Pursuant to 37 C.F.R. § 1.136(a), a request for a one-month extension of time is concurrently filed, bringing the due date for this response to March 7, 2007. Should such a request be deficient or absent, consider this such a request and authorization to withdraw the application fee from Fulbright & Jaworski Deposit Account No.: 50-1212/UTSD:798US.

The Office is further authorized to treat any concurrent or future reply that requires a petition for an extension of time under 37 C.F.R. § 1.136(a) to be timely as incorporating a petition for an extension of time for the appropriate length of time, and to deduct all required fees under 37 C.F.R. §§ 1.16 to 1.21 relating to any such replies of other relevant papers from Fulbright & Jaworski Deposit Account No.: 50-1212/UTSD:798US.

K. Conclusion

The pending claims are in condition for allowance. The Examiner is invited to contact the undersigned attorney at (512) 536-3031 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

/Mark T. Garrett/

Mark T. Garrett
Reg. No. 44,699
Attorney for Applicant

FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201
(512) 536-4598 (facsimile)
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